REMARKS

THE CLAIMS

Claims 1-51 were filed with the application, claims 2-51 were canceled by the application filing form, claim 1 is being canceled hereby, and claims 52 to 64 substituted therefore. Accordingly, claims 52-64 are now active in this case. The amendments to the claims are fully supported by the specification of the parent application as filed, and by the original claims. No objectionable new matter is believed to have been introduced hereby.

THE SEQUENCE LISTING

A paper version of the Sequence Listing was submitted when the application was filed, along with a sworn declaration and a request that the computerized version thereof be transferred from the parent application. is believed to place this application in conformity with the requirements of 37 CFR 1.821-1.825. Consideration thereof is hereby requested.

GENERAL COMMENTS

The applicant is submitting new claims provided as substitute pages 50-60, and substitute pages 1 and 61 reflecting amendments to the specification. These amendments are believed by the applicant not to introduce any new matter into this application.

In view of the foregoing amendments and remarks, this application is believed to be in condition for examination on the merits, and for allowance.

Respectfully submitted.
CANCER RESEARCH INSTITUTE

3/10/03
Date

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WHAT IS SEEKED TO BE PATENTED AS NOVEL & UNOBVIOUS IN LETTERS PATENT OF THE UNITED STATES IS:

52. A specifically targeted antibody agent, comprising a monoclonal antibody selectively binding the 46 Kd MW human milk fat globule (HMFG) differentiation antigen, which has an affinity constant for the antigen of about 10^{10} to 10^{5} M^{-1}, operatively linked to an agent comprising an immunotoxin or a detectable label.

53. The antibody agent of claim 97, wherein the label comprises a radionucleide.

54. The antibody agent of claim 97, wherein the label comprises a fluorophore.

55. The antibody agent of claim 97, wherein the antibody comprises a monoclonal antibody.

56. A composition comprising the antibody agent of claim 97, and a non proteolytic carrier.

57. The composition of claim 99, wherein the carrier comprises a biologically acceptable carrier.

58. The composition of claim 100, wherein the carrier comprises a pharmaceutically acceptable carrier.

59. An anti-neoplastic kit comprising the specifically targeted antibody agent of claim 97, and instructions for its use.

60. An anti-neoplastic kit comprising, in separate containers,
the monoclonal antibody of claim 52;
an agent comprising an immunotoxin(s) or a radionucleide(s); and
instructions for operatively linking the monoclonal antibody and the agent, and for the use of the kit.

61. An in vivo method of imaging a neoplasia of epithelial origin, comprising

administering to a subject suspected of being afflicted with a neoplasia an amount of the agent of claim 52 under conditions effective to deliver it to target neoplastic cells of epithelial origin in the subject's body to form antibody-cell antigen complexes;

administering to the subject a detectable label binding the antibody at a site other than the binding site for the 46 Kdalton HMFG polypeptide; and

detecting the presence of any label in the subject's body.

62. An in vivo method of delivering a therapeutic agent to target neoplastic cells of epithelial origin, comprising

binding a therapeutic agent to the antibody of claim 52 at a site other than its antigen binding site;

administering to a subject suspected of being afflicted with a neoplasia of epithelial origin, a therapeutically effective amount of the antibody-bound therapeutic agent under conditions effective to deliver the agent to target neoplastic cells; and

allowing the antibody to bind to the neoplastic cells and the therapeutic agent to exert its effect on the cells.

63. An ex vivo method of delivering a therapeutic agent to target neoplastic cells, comprising

obtaining a sample from a subject suspected of being afflicted with a neoplasia of epithelial origin;

adding the therapeutic agent of claim 52, to the sample under conditions effective to promote the formation of antibody-cell complexes;

allowing the agent to exert its effect on the cells; and

returning the sample to the subject.

64. The method of claim 63, further comprising separating antibody-bound materials from the sample prior to returning it to the subject.

SPECIFICALLY TARGETED ANTIBODY AGENT, COMPOSITION, KIT & RELATED USES

ABSTRACT OF THE DISCLOSURE

A specifically targeted antibody agent, comprises a monoclonal antibody selectively binding the 46 Kdalton human milk fat globule (HMFG) differentiation antigen, which has an affinity constant for the antigen of about 10^{10} to 10^{5} M^{-1}, operatively linked to an agent comprising an immunotoxin or a detectable label. An anti-neoplastic kit comprises the monoclonal antibody, the agent, and instructions for assembly and use. An in vivo method for imaging a neoplasia comprises delivering the antibody, allowing it to bind, administering to the subject a detectable agent that binds to the antibody at a site other that the antigen or cell binding site, and detecting the presence of any label in the subject's body. An in vivo method for delivering a therapeutic agent to target neoplastic cells comprises binding the antibody of claim 52 to the agent at a site other than the antigen binding site, administering it to a subject in need of treatment, and allowing the antibody to bind to the neoplastic cells, and the therapeutic agent to exert its effect.

B4

Substitute Page 61 (marked up)

SPECIFICALLY TARGETED ANTIBODY AGENT, COMPOSITION, KIT & RELATED USES

[POLYPEPTIDE WITH 46 DALTON HMFG DIFFERENTIATION ANTIGEN BINDING SPECIFICITY AND CLOTTING FACTORS V AND VIII LIGHT-CHAIN HOMOLOGIES, FUSION PROTEIN, POLYNUCLEOTIDE, AND POLYRIBONUCLEOTIDE ENCODING THE POLYPEPTIDE, ANTI-POLYPEPTIDE ANTIBODIES, KITS, AND METHODS OF USE THEREOF Abstract of the Disclosure]

ABSTRACT OF THE DISCLOSURE

A specifically targeted [polypeptide has the] antibody agent, comprises a monoclonal antibody selectively binding [activity of] the 46 Kdalton human milk fat globule (HMFG) differentiation antigen, which has an affinity constant for the antigen of about 10^{10} to 10^{5} M^{-1}, operatively linked to an agent comprising an immunotoxin or a detectable label [and/or homology to at least one of the light chains of clotting factors V and VIII and is also provided as a fusion protein with a second antigenic polypeptide. An antibody has affinity for the polypeptide of the invention or a functional fragment thereof.] An anti-neoplastic kit comprises the monoclonal antibody, the agent, and instructions for assembly and use. An in vivo [and in vitro] method [s] for [therapy vaccination] imaging a neoplasia comprises delivering the antibody, allowing it to bind, administering to the subject a detectable agent that binds to the antibody at a site other that the antigen or cell binding site, [y vaccination] and detecting the presence of any label in the subject's body [the polypeptide]. An in vivo method for delivering a therapeutic agent to target neoplastic cells comprises binding the antibody of claim 52 to the agent at a site other than the antigen binding site, administering it to a subject in need of treatment, and allowing the antibody to bind to the neoplastic cells, and the therapeutic agent to exert its effect.

[, the antibody, the DNA and RNA of the invention are provided. DNA and RNA sequences encode the polypeptide of the invention or fragments thereof and immunoassay kits comprise the antibodies and/or polypeptides of the invention.]

SPECIFICALLY TARGETED ANTIBODY AGENT, COMPOSITION, KIT & RELATED USES

BACKGROUND OF THE INVENTION

Related Patents

This application is a divisional of US Patent Application Serial No. 08/482,596, issue fee paid January 2, 2002; which is a divisional of US Patent Application Serial No. 07/607,538, now US Patent No. 5,455,031, and US Patent Application Serial No. 08/162,402 filed December 3, 1990, now US Patent No. 5,972,337.

Technical Field

This invention relates to a polypeptide having the antibody binding specificity of the 46 kDalton HMFG differentiation antigen, a polynucleotide, and a polyribonucleotide encoding it, anti-polypeptide antibodies, methods of detecting the polypeptide and DNA and RNA encoding it, a method of imaging cells expressing the polypeptide, a method of detecting the presence of the polypeptide in a biological fluid by binding the antibody to the polypeptide, in vivo and ex vivo methods of delivering a therapeutic agent to a target cell expressing the polypeptide, a fusion protein of the polypeptide and at least one other polypeptide, labeled polynucleotides and polyribonucleotides encoding the polypeptide and a complementary DNA sequence, method of detecting RNA and DNA by hybridization with labeled probes, a method of vaccination with the polypeptide, and method of treating breast cancer with an anti-sense DNA.

1642

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appl. of: Ceriani et al. : Appl. Ref. No.: CRFC-047

Serial No.: 10/038,252 :

Filing Date: January 2, 2002 : Examiner: Dr M.T.Davis

Title: **POLYPEPTIDE WITH 46 KDALTON HMFG DIFFERENTIATION ANTIGEN BINDING SPECIFICITY AND CLOTTING FACTORS V AND VIII LIGHT-CHAIN HOMOLOGIES, FUSION PROTEIN, POLYNUCLEOTIDE, & POLYRIBONUCLEOTIDE ENCODING THE POLYPEPTIDE, ANTI-POLYPEPTIDE ANTIBODIES, KITS AND METHODS OF USE THEREOF**

COVER LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir/Madam:

Enclosed for filing are the following:

1. Supplemental Preliminary Amendment (2 pages)
2. Claims (2 pages)
3. Substitute Page 1 (2 pages)
4. Substitue Page 61 (2 pages)
5. This cover sheet
6. Stamped, Sslf-addressed post-card

Respectfully submitted,
CANCER RESEARCH INSTITUTE

March 10, 2003
Date

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail under 37 CFR 1.8 in an envelope addressed to the Assistant Commissioner for Patents, Washington D C 20231 on March 10, 2003, by Viviana Amzel.

SIGNATURE

Substitute Page 1 (marked-up)

SPECIFICALLY TARGETED ANTIBODY AGENT, COMPOSITION, KIT & RELATED USES

BACKGROUND OF THE INVENTION

Related Patents

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[POLYPEPTIDE WITH 46 KDALTON HMFG DIFFERENTIATION ANTIGEN BINDING SPECIFICITY AND CLOTTING FACTORS V AND VIII LIGHT-CHAIN HOMOLOGIES, FUSION PROTEIN, POLYNUCLEOTIDE, AND POLYRIBONUCLEOTIDE ENCODING THE POLYPEPTIDE, ANTI-POLYPEPTIDE ANTIBODIES, KITS AND METHODS OF USE THEREOF]

Technical Field

This invention relates to a polypeptide having the antibody binding specificity of the 46 kDalton HMFG differentiation antigen, a polynucleotide, and a polyribonucleotide encoding it, anti-polypeptide antibodies, methods of detecting the polypeptide and DNA and RNA encoding it, a method of imaging cells expressing the polypeptide, a method of detecting the presence of the polypeptide in a biological fluid by binding the antibody to the polypeptide, in vivo and ex vivo methods of delivering a therapeutic agent to a target cell expressing the polypeptide, a fusion protein of the polypeptide and at least one other polypeptide, labeled polynucleotides and polyribonucleotides encoding the polypeptide and a complementary DNA sequence, method of detecting RNA and DNA by hybridization with labeled probes, a method of vaccination with the polypeptide, and method of treating breast cancer with an anti-sense DNA.